


**IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE**

| | | | |
|----------------------|-----------------------|---|--|
| Applicants: | Erik H.F. Wong et al. |) | I hereby certify that this paper is being |
| Serial No.: | To be assigned |) | deposited with the United States Postal |
| Filed: | January 16, 2004 |) | Service, on January 16, 2004 , in an |
| | (Herewith) |) | envelope addressed to Mail Stop Patent |
| Title: | METHOD OF TREATING OR |) | Application, Commissioner for Patents, |
| | PREVENTING PERIPHERAL |) | P.O. Box 1450, Alexandria, Virginia |
| | NEUROPATHY WITH A |) | 22313-1450, utilizing the "Express Mail |
| | HIGHLY SELECTIVE |) | Post Office to Addressee" service of the |
| | NOREPINEPHRINE |) | United States Postal Service under |
| | REUPTAKE INHIBITOR |) | Mailing Label No. EL566462191US . |
| Group Art Unit: | To be assigned |) | |
| Examiner: | To be assigned |) | |
| Attorney Docket No.: | 30744/6248.11 |) |  Richard Zimmermann |

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

The above-identified application is a division of, and claims priority benefit under 35 U.S.C. § 120 to, pending U.S. patent application Serial No. 10/255,450 (filed September 26, 2002), which itself is a division of, and claims priority benefit under § 120 to, U.S. patent application Serial No. 09/599,213 (filed June 22, 2000) now U.S. Patent No. 6,465,458.

Pursuant to 37 C.F.R. § 1.97(b), enclosed herewith is a completed Form PTO-1449 identifying documents that may be considered material to the examination of the above-identified application. Also enclosed herewith and identified on the enclosed Form PTO-1449 are copies of the following publications:

- (a) U.S. Patent No. 6,465,458;
- (b) U.S. Patent No. 6,610,690, which issued on August 26, 2003, from U.S. patent application Serial No. 10/037,344, which is a division of, and claims priority benefit under § 120 to, the '213 application;

(c) U.S. Patent No. 6,642,235, which issued on November 4, 2003, from U.S. patent application Serial No. 10/099,334, which is a division of, and claims priority benefit under § 120 to, the '213 application;

(d) U.S. Patent Application Publication No. 2002/0061910 A1 for U.S. patent application Serial No. 10/020,261, published on May 23, 2002, which is a division of, and claims priority benefit under § 120 to, the '213 application;

(e) U.S. Patent Application Publication No. 2002/0107249 A1 for U.S. patent application Serial No. 10/055,663, published on August 8, 2002, which is a division of, and claims priority benefit under § 120 to, the '213 application;

(f) U.S. Patent Application Publication No. 2003/0040464 A1 for U.S. patent application Serial No. 10/255,450, published on February 27, 2003, which is a division of, and claims priority benefit under § 120 to, the '213 application.

Pursuant to 37 C.F.R. § 1.98(d), copies of the other documents identified on the accompanying Form PTO-1449 are not being enclosed as each was previously submitted during prosecution of the '213 application. However, the applicants will be pleased to provide additional copies should the examiner so desire.

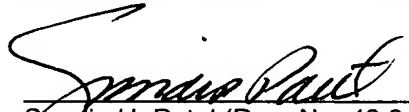
An early and favorable action on the merits is respectfully requested.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN LLP

January 16, 2004

By:


Sandip H. Patel (Reg. No. 43,848)
Attorneys for Applicants
6300 Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606-6357
(312) 474-6300 TELEPHONE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|---|---|--------------------------|-----------------------------|------------------------|---------------|
| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | Complete if Known | | | |
| | | Application Number | | | |
| | | Filing Date | January 16, 2004 (Herewith) | | |
| | | First Named Inventor | Erik H.F. Wong | | |
| | | Art Unit | | | |
| | | Examiner Name | | | |
| Sheet | 1 | of | 3 | Attorney Docket Number | 30744/6248.11 |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Date Filed if Appropriate |
|-----------------------|---|--------------------------------|--|---------------------------|
| | 4,229,449 | 10-21-80 | Melloni et al. | |
| | 4,596,807 | 06-24-86 | Crosby | |
| | 5,068,433 | 11-26-91 | Melloni et al. | |
| | 5,192,751 | 03-09-93 | Thor | |
| | 5,281,624 | 01-25-95 | Gehlert et al. | |
| | 5,391,735 | 02-21-95 | Melloni et al. | |
| | 5,441,985 | 08-15-95 | Foreman | |
| | 5,744,474 | 04-28-98 | Thor | |
| | 5,922,914 | 07-13-99 | Gage et al. | |
| | 5,998,430 | 12-07-99 | Schwantes et al. | |
| | 6,028,070 | 02-22-00 | Heiligenstein | |
| | 6,046,193 | 04-04-00 | Heiligenstein | |
| | 6,066,643 | 05-23-00 | Perry | |
| | 4,465,458 | 10-15-02 | Wong et al. | |
| | 6,610,690 | 08-26-03 | Wong et al. | |
| | 6,642,235 | 11-04-03 | Wong et al. | |
| | 2002-0061910-A1 | 05-23-02 | Wong et al. | 12-14-01 |
| | 2002-0107249-A1 | 08-08-02 | Wong et al. | 01-23-02 |
| | 2003-0040464-A1 | 02-27-03 | Wong et al. | 09-26-02 |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Foreign Patent Document Country Code-Number-Kind Code (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | |
|-----------------------|---|--------------------------------|--|--|
| | 2,014,981 | 09-05-79 | Great Britain | |
| | 2,167,407 | 05-11-88 | Great Britain | |
| | WO 96/12485 | 05-02-96 | PCT | |
| | WO 97/35584 | 10-02-97 | PCT | |
| | WO 97/35586 | 10/02/97 | PCT | |
| | WO 99/15163 | 04-01-99 | PCT | |
| | WO 99/15176 | 04-01-99 | PCT | |
| | WO 99/15177 | 04-01-99 | PCT | |
| | WO 99/20279 | 04-29-99 | PCT | |
| | WO 99/52531 | 10-21-99 | PCT | |
| | WO 99/52518 | 10-21-99 | PCT | |
| | WO 99/58130 | 11-18-99 | PCT | |
| | WO 01/26623 | 04-19-01 | PCT | |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| Examiner Initials | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published. | |
|----------------------|--|--|
| | J.J. Schildkraut, The Catecholamine Hypothesis of Affective Disorders: A Review of Supporting Evidence, Am. J. of Psychiatry, Vol. 122, pp. 509-22 (Nov. 1965). | |
| | T.H. Svensson, et al., Feedback Inhibition of Brain Noradrenaline Neurons by Tricyclic Antidepressants: a-Receptor Mediation, Science, Vol. 202, pp. 1089-91 (1984). | |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|---|---|----|---|--------------------------|-----------------------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | |
| | | | | Filing Date | January 16, 2004 (Herewith) |
| | | | | First Named Inventor | Erik H.F. Wong |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 2 | of | 3 | Attorney Docket Number | 30744/6248.11 |

| | | |
|--|--|--|
| | E. Richelson et al., Blockade by Antidepressants and Related Compounds of Biogenic Amine Uptake into Rat Brain Synaptosomes: Most Antidepressants Selectively Block Norepinephrine Uptake, <i>Europ. J of Pharmacology</i> , Vol. 104 pp. 277-86 (1984). | |
| | C.B. Nemeroff, <i>The Neurobiology of Depression</i> , <i>Scientific American</i> (1988) (8 pages). | |
| | M. Riva et al., Effect of Reboxetine, A New Antidepressant Drug, on the Central Noradrenergic System: Behavioral and Biochemical Studies, <i>J. Drug Dev.</i> , Vol. 1, no. 4, pp. 243-53 (1989). | |
| | T. Pacholczyk et al., Expression Cloning of a Cocaine-and Antidepressant-Sensitive Human Noradrenaline Transporter, <i>Nature</i> , Vol. 350, no. 28, pp. 350-56 (March 1991). | |
| | M. Max et al., Efficacy of Desipramine in Painful Diabetic Neuropathy: A Placebo-Controlled Trial, <i>Pain</i> , Vol. 45, pp. 3-9 (1991). | |
| | E. Richelson, Biological Basis of Depression and Therapeutic Relevance, <i>J. Clin. Psychiatry</i> , Vol. 52, no. 6 Suppl., pp. 4-10 (June 1991). | |
| | M. Max et al., Effects of Desipramine Amitriptyline and Fluoxetine on Pain in Diabetic Neuropathy, <i>New Engl. J. Med.</i> , Vol. 326, No. 19, pp. 1250-56 (1992). | |
| | B. Cusack et al., Binding Antidepressants to Human Brain Receptors: Focus on Newer Generation Compounds, <i>Psychopharmacology</i> , Vol. 114, pp. 559-65 (1994). | |
| | M. Max, "Treatment of Post-Herpetic Neuralgia: Antidepressants," <i>Ann. Neurol.</i> , Vol. 35, Suppl., pp. s50-s53 (1994). | |
| | W. Reimann et al., "Inhibition of Spinal Noradrenaline Uptake in Rats by the Centrally Acting Analgesic Tramadol," <i>Biochem. Pharmacol.</i> , Vol. 47, No. 12, pp. 2289-93 (1994). | |
| | C. Pellizzoni et al., Pharmacokinetics of Reboxetine in Healthy Volunteers. Single Against Repeated Oral Doses and Lack of Enzymatic Alterations, <i>Biopharm. Drug Dispos.</i> Vol. 17. No. 7, pp. 623-33 (1996). | |
| | R.J. Baldessarini, Depression and Mania, Goodman & Gilman's <i>The Pharmacological Basis of Therapeutics</i> , 9 th Ed., Chapter 19, pp. 431-39, (1996) | |
| | B.E. Leonard, Noradrenaline in Basic Models of Depression, <i>European Neuropsychopharmacology</i> , Vol. 7, Suppl. 1, pp. S11-S16 (1997). | |
| | Discussion, <i>European Neuropsychopharmacology</i> , Vol. 7, Suppl. 1, pp. S71-S73 (1997). | |
| | S.A. Montgomery, Is There a Role For a Pure Noradrenergic Drug in the Treatment of Depression?, <i>Eur. Neuropsychopharmacology</i> , Vol. 7, Suppl. 1, pp. S3-S9 (1997). | |
| | S.A. Montgomery, Reboxetine: Additional Benefits to the Depressed Patient, <i>J. Psychopharmacology (Oxf)</i> , 11:4 Abstract (1997). | |
| | I. Hindmarch, The Effects of Antidepressants on Psychomotor Function With Particular Reference to Reboxetine, <i>Eur. Neuropsychopharmacology</i> , Vol. 7, Suppl. 1, pp. S17-S21 (1997). | |
| | E. Frigerio et al., Pharmacokinetics of Reboxetine Enantiomers in the Dog, <i>Chirality</i> , Vol. 9, pp. 303-06 (1997). | |
| | A. Frazer, Pharmacology of Antidepressants, <i>J. Clinical Psychopharmacology</i> , Vol. 17, no. 2, Suppl. 1, pp. 2S-18S (1997). | |
| | B. E. Leonard, The Role of Noradrenaline in Depression: a Review, <i>J. Psychopharmacology</i> , Vol. 11, no. 4 Suppl., pp. S39-S47 (1997). | |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|---|---|----|---|--------------------------|-----------------------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | |
| | | | | Filing Date | January 16, 2004 (Herewith) |
| | | | | First Named Inventor | Erik H.F. Wong |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 3 | of | 3 | Attorney Docket Number | 30744/6248.11 |

| | | |
|--|---|--|
| | Dostert et al., Review of the Pharmacokinetics and Metabolism of Reboxetine, a Selective Noradrenaline Reuptake Inhibitor," Euro. Neuropsychopharmacol., Vol. 7, Suppl. 1, pp. s23-s35 (1997). | |
| | M. Owens et al., "Neurotransmitter Receptor and Transporter Binding Profile of Antidepressants and Their Metabolites," J. Pharmacol. Exp. Ther., Vol. 283, pp. 1305-1322 (1997). | |
| | D. Healy et al., The Clinical Pharmacologic Profile of Reboxetine: Does it Involve the Putative Neurobiological Substrate of Wellbeing?, J. of Affective Disorders, Vol. 51, pp. 313-22 (1998). | |
| | Anonymous, Reboxetine – Another New Antidepressant, Drugs and Therapeutics Bull., 36 (11) (1998). | |
| | S.A. Montgomery, The Place of Reboxetine in Antidepressant Therapy, J. of Clinical Psychiatry, Vol. 59, Suppl. 14, pp. 26-29 (1998). | |
| | G.D. Burrows et al., Antidepressant Efficacy and Tolerability of the Selective Norepinephrine Reuptake Inhibitor Reboxetine: A Review, J. Clin. Psychiatry, Vol. 59, Suppl. 14, 4 pages (1998). | |
| | J. Massana, Reboxetine Versus Fluoxetine: An Overview of Efficacy and Tolerability, J. Clin. Psychiatry, Vol. 59, Suppl. 14, pp. 8-10 (1998). | |
| | A. Harkin et al., Activity and Onset of Action of Reboxetine and Effect of Combination With Sertraline in an Animal Model of Depression, Eur. J. of Pharmacology, pp. 1-10 (1998). | |
| | J. Massana et al., Reboxetine: A Double-Blind Comparison With Fluoxetine in Major Depressive Disorder, Int. Clin. Psychopharmacol, Vol. 14, No. 2, pp. 73-80 (1999). | |
| | J.C. Fleishaker et al., Absolute Bioavailability of Reboxetine Enantiomers and Effect of Gender on Pharmacokinetics, Biopharm. Drug Dispos. Vol. 20, no. 1, pp. 53-57 (1999). | |
| | K. Moore et al., "Tissue Distribution of Tramadol and Metabolites in an Overdose Fatality," Am. J. of Forensic Med. and Path., Vol. 20, No. 1, pp. 98-100 (1999). | |
| | S. Kasper, From Symptoms to Social Functioning: Differential Effects of Antidepressant Therapy, International Clinical Psychopharmacology, Vol. 14, Suppl. 1, pp. S27-S31 (May 1999). | |
| | J. Mark Ruscin and Nora E. Morgenstern, "Tolterodine Use for Symptoms of Overactive Bladder," The Annals of Pharmacotherapy, Abstract Vol. 33, pgs. 1073-82 (October 1999). | |
| | International Search Report in PCT/US00/17256 dated July 12, 2001. | |
| | International Preliminary Examination Report in PCT/US00/17256 dated December 19, 2001. | |
| | "Notice of Allowance and Fee(s) Due" dated March 25, 2003, sent by the United States Patent and Trademark Office for U.S. Serial No. 10/037,344 (4 pages). | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.